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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,020	02/10/2004	Gregory B. Altshuler	105090-0234	2206

21125 7590 09/30/2005

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EXAMINER
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JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,020	<b>Applicant(s)</b> ALTSHULER ET AL.	
	<b>Examiner</b> Henry M. Johnson, III	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 012805 020705
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities:

In paragraph 01, the word claim should be claims in lines 1 and 7.

In paragraph 01, the patent number is required for 09/996,662.

Appropriate correction is required.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-16, 18, 19 and 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6-9, 22-29, 32, 33 and 35-40 of copending Application No. 10/776686. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 6-16 and 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, 22-

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29 and 36-39 of copending Application No. 10/776687. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 6-16 and 18-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9-23, 25-32 and 34-46 of copending Application No. 10/777022. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

The claims objected to because of the following informalities: an applicator is claimed, yet the dependent claims cite an apparatus. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the radiation emitting element" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 11, 16, 18, 19-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended time (Page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as an inherently compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge or filament bulb ((page 3, lines 30-32). The source may be mounted on the mouthpiece or external and delivered via fiber optics. The means for delivery can include a diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15). Portions of the mouthpiece may be highly reflective (page 7, line 21). Chen et al. incorporates by reference U.S. Patent 5,445,608 ('608) that teaches the use of either an internal or external array of light sources also allows incorporation of LEDs or LDs operating at two or more wavelengths or wavebands, and the ability to selectively activate the LEDs or LDs operating at a given wavelength or waveband as desired, so that light at the different wavelengths or wavebands is provided to the treatment site either sequentially or simultaneously from the light source (Col. 8, lines 37-45). The sources may be

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controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 16, line 8).

The current regulation will control the power of the light source.

Regarding claim 8, the disclosure of a gas discharge source inherently produces a polychromatic radiation. Chen et al. teach specific wavelengths for treatment and therefore it is inherent filters would be employed to obtain the desire wavelength when using a polychromatic source.

Regarding claim 11, the sources must be mounted to some structure, all of which have an inherent heat dissipating capability.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

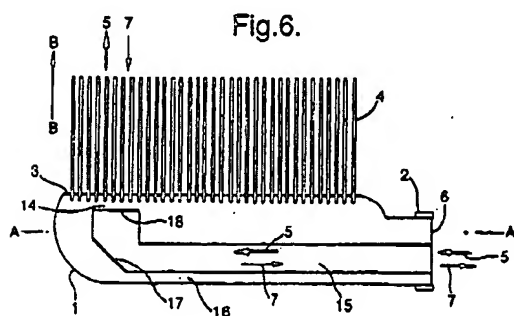
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9-10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 5,133,120 to Sakuma. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the

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handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to



the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is

interpreted as a diagnostic sensor (Col. 2, lines 38-65). The apparatus is clearly capable of radiating any area within an oral cavity. The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The bristles are interpreted as capable of conforming to a portion of the oral cavity (the teeth). Muller does not teach the use of a contact sensor. Sakuma discloses an electronic toothbrush with a handle, head and bristles and a circuit that energizes a radiation device when the bristles contact the teeth, thus sensing contact and completing the circuit via the body of the user. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the contact sensor as taught by Sakuma in the device of Muller to activate the device when in the preferred use position, in contact with the oral tissue.

Claims 1, 11, 13, 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 4,333,197 to Kuris. Muller is discussed above, but does not teach the use of heat sinks or ultrasonics, although the handle of Muller would inherently transfer heat from the radiation source in the handle to the rest of the device body and head because virtually all materials have some heat transfer capacity. Kuris

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teaches an ultrasonic toothbrush with a handle, head and bristles driven by ultrasonic frequencies (abstract). The handle is designed to remove the heat produced by the ultrasonic generator (Col. 4, lines 28-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ultrasonic generator and heat removal techniques as taught by Kuris in the device of Muller to complement the hygienic process within an oral cavity.

Claims 12 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 4,333,197 to Kuris as applied to claim 11 above, and further in view of U.S. Patent 6,350,276 to Knowlton. Muller and Kuris are both discussed above, but do not disclose cooling using fluids or phase changing substances. Knowlton discloses an apparatus for treating tissue using energy sources that may be light (Col. 7, lines 55-56). Figure 5, from a cross-referenced (and incorporated) Knowlton patent (6,425,912), teaches energy sources (Fig. 5, # 18) that conform to the skin. Knowlton teaches cooling of the sources and tissue using a liquid (Fig. 2B, # 15) that can be in a liquid or gaseous state, or may exist in two or more phases and may undergo a phase change as part of its cooling function (Col. 5, lines 29-35), such as melting or evaporation (whereby heat is absorbed by the fluid as a latent heat of fusion or evaporation). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cooling methodologies as taught by Knowlton et al. in the invention of Muller as modified by Kuris if the radiation sources require cooling as the fluid and phase change methods are common and known.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/06456 to Chen et al. as applied to claim 1 above, and further in view of U.S. Patent 4,862,903 to Campbell. Chen et al. is discussed above, but does not teach a lumen in the mouthpiece. Campbell discloses a mouthpiece for use with a snorkel or dive regulator with an airway lumen



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(Fig. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the airway lumen as taught by Campbell in the mouthpiece of Chen et al. to facilitate breathing. Motivation would be clear if the mouthpiece impeded breathing or if the intended patient had congestion that precluded breathing via the nose.

Claims 1 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 5,658,148 to Neuberger et al. Muller is discussed above, but does not teach ports for delivery of agents via the device. Neuberger et al. teach a dental brush with an optical fiber (Fig. 2, # 21) that carries radiation from a radiation source and water or liquid passage (Fig. 2, # 22) that carries water or liquid under pressure to the brushhead (Col. 3, lines 25-28). The port is capable of delivering a drug. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an agent delivery means as taught by Neuberger et al. in the invention of Muller as drug for use as photosensitizers are pervasive in the photodynamic therapy arts.

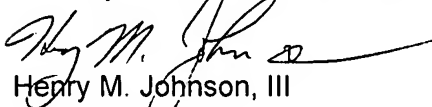
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Patent Examiner  
Art Unit 3739